

Dockets Management Branch
The Food and Drug Administration
Department of Health & Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Date: Feb. 28, 1990

Re: **99P-1340/CP 1** — Petition to Have *Eternity eau de parfum* declared "Misbranded" 2754 00 MAR -6 A9:53

Dear Sir or Madam:

In May 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's *Eternity eau de parfum* declared "misbranded." I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 states:

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

"Warning — The safety of this product has not been determined."

As the petition shows, *Eternity* contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as *Eternity* so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including: people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, caregivers and teachers. When I am exposed to **fragrance products** I can experience any of the following symptoms based upon the chemical fragrance product I encounter:

- | | | | |
|---|---|--|---|
| <input type="checkbox"/> anaphylaxis/shock | <input type="checkbox"/> double vision | <input checked="" type="checkbox"/> incoherence | <input checked="" type="checkbox"/> nausea stomach distress |
| <input checked="" type="checkbox"/> anxiety, restlessness | <input type="checkbox"/> ear pain | <input checked="" type="checkbox"/> incontinence | <input type="checkbox"/> nose bleeds |
| <input type="checkbox"/> asthma | <input type="checkbox"/> eczema | <input checked="" type="checkbox"/> irritability | <input type="checkbox"/> rashes |
| <input checked="" type="checkbox"/> breathing difficulty | <input type="checkbox"/> eyes, watery or dry | <input checked="" type="checkbox"/> joint aches | <input type="checkbox"/> seizures |
| <input type="checkbox"/> bronchitis | <input checked="" type="checkbox"/> fatigue | <input type="checkbox"/> laryngitis | <input checked="" type="checkbox"/> short-term mem. loss |
| <input checked="" type="checkbox"/> can't concentrate | <input type="checkbox"/> flushing | <input checked="" type="checkbox"/> lethargy | <input type="checkbox"/> sinusitis |
| <input type="checkbox"/> coughing | <input checked="" type="checkbox"/> headaches | <input type="checkbox"/> lymph nodes swell | <input type="checkbox"/> sneezing |
| <input checked="" type="checkbox"/> depression | <input checked="" type="checkbox"/> heart beat irregularity | <input checked="" type="checkbox"/> mood swings | <input type="checkbox"/> sores, skin/mouth |
| <input checked="" type="checkbox"/> disorientation | <input type="checkbox"/> hives | <input checked="" type="checkbox"/> muscle pain/weakness | <input type="checkbox"/> swallowing difficulty |
| <input checked="" type="checkbox"/> dizziness | <input type="checkbox"/> hypertension | <input type="checkbox"/> nasal congestion | <input type="checkbox"/> tinnitus |
| <input type="checkbox"/> other: _____ | | | |

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Toxic chemicals in fragrances have already ruined countless lives. Thank you.

Sincerely,

Joanne M Baek

Your name JOANNE M BAEK

3140 Wood Rd #2, Racine WI 53406

address, city/st/zip

C 588

99P-1340

Newsletters and everyone who feels people have a right to know, please copy, share, tell your friends and WRITE the FDA today!

additional symptoms I experience include:

compulsive and impulsive behavior

episodes of rage, violence

tremors, shaking, episodes of sudden strong shivers

loss of capacity for judgement

loss of visual comprehension; can see but not understand what is seen...

— ADDENDUM —

Consumers should be informed if a product is unsafe. In the case of fragrances, not only do we know that their safety has not been ~~determined~~, but we also know that they are unsafe. The testimony of hundreds of affected persons has told you so. The warnings you have authorized to be put on products are inadequate. An appropriate warning would have to include "... WILL cause injury to others ... [AND] SHOULD NOT BE USED."

The appropriate action for the FDA to take to protect human health is to ban and issue a recall for all fragrance containing products, period.

Jeanne M. Bach

Joanne Baek
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